DEPARTMENT OF THE ARMY
OFFICE OF THE SURGEON GENERAL
5109 LEESBURG PIKE
FALLS CHURCH VA 22041-3258

REPLY TO
ATTENTION OF

MCMR-RCQ (70-1n)

14 August 2002

HSRRB Policy Memorandum 2002-05, Version 01

SUBJECT: Ethical Use of Human Cadavers in Research

1. REFERENCES.

a. 32 CFR 219, *Protection of Human Subjects*

b. AR 70-25, *Use of Volunteers as Subjects of Research*, 25 January 1990

c. *Uniform Anatomical Gift Act*, drafted by National Conference of Commissioners of Uniform State Laws, 1987

d. Command Policy 2001-04, *Ethical Use of Human Cadavers in USAMRMC Research*, 23 August 2001

2. HISTORY. This is the first version of The Army Surgeon General's Human Subjects Research Review Board (HSRRB) Policy Memorandum 2002-05. This version is effective 3 September 2002. Details of the history can be found in Appendix A.

3. PURPOSE. This memorandum establishes the HSRRB policy for the proper procurement, treatment, and disposition of human cadavers in any research submitted to the HSRRB for review. This includes, but is not limited to, any intramural or extramural research conducted or managed by the U.S. Army Medical Research and Materiel Command (USAMRMC), any research conducted in USAMRMC facilities, and any research conducted by USAMRMC personnel as part of their USAMRMC duties.

a. The HSRRB believes that it is necessary to provide oversight of research using human cadavers. Human cadavers should be treated with respect, and should not be used in research if alternatives are available.

b. Neither the Common Rule (adopted by the Department of Defense as 32 CFR 219) nor AR 70-25 applies to research using human cadavers. Both of these regulations apply to "human subjects" and both define "human subject" as a "living individual". Although neither Common Rule nor AR 70-25 mandate Institutional Review Board (IRB) review for research using human cadavers, the existence of ethical concerns and regulatory requirements in research using human cadavers, and the often high-profile nature of such research, counsel in favor of requiring IRB review.

4. SCOPE. This policy is applicable to any research using human cadavers that is submitted to the HSRRB for review. This includes, but is not limited to, intramural and extramural research using human cadavers that is conducted or managed by USAMRMC, conducted in USAMRMC facilities, or conducted by USAMRMC personnel as part of their USAMRMC duties.

5. DEFINITION OF TERMS.

a. Human Cadaver. The term "cadaver" means a deceased person or portion thereof. The term "cadaver" includes organs, tissue, eyes, bones, arteries, blood, fluid or other portion of a deceased person. The term "cadaver" does not include portions of an individual, such as tissue or blood, that were removed from the individual for research purposes while the individual was still alive (for example, if a subject of an earlier research protocol donated tissue taken from him or her during that protocol for use in future research protocols, that tissue is not a "cadaver" under this policy, regardless of whether the individual is still living or has died prior to the current research protocol). This policy applies only to research using donations that take effect upon or after the death of an individual.

b. Research. The term "research" has the same definition as in 32 CFR 219: "A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."

6. POLICY.

a. Intramural research protocols involving the use of human cadavers require review and recommendation for approval by the local Scientific Review Committee (SRC) and Human Use Review Committee (HURC). If there is no formal SRC, scientific review is still necessary, but may be done by some other qualified committee or personnel. Extramural research protocols require scientific review. Extramural research protocols also must receive review and approval from the institution's IRB if it is the policy of that IRB to review research involving the use of human cadavers. If approved at the local level, the protocol must be forwarded to The Surgeon General's Human Subjects Research Review Board (HSRRB) for review. No research that is subject to this policy will be conducted without approval from the HSRRB, either through expedited review or full Board review if deemed necessary.

b. For intramural research, the Principal Investigator (PI) will provide copies of state and local laws (or, for research in a foreign country or U.S. territory, that country's or territory's laws) regarding procurement, treatment, and disposition of the human cadavers requested for the research protocol to the respective human use committees involved in the review and approval of the PI's research protocol. Note that the Uniform

Anatomical Gift Act has been adopted in some form in all states and the District of Columbia. The HURC will ensure that any relevant laboratory/institution policies are being and will be followed. For extramural research, either the PI or the IRB will provide copies of state and local laws (or foreign or U.S. territory laws) to the HSRRB. Neither the HURC nor the HSRRB will approve any research protocol unless it is satisfied that applicable laws regarding human cadavers have been and are being followed.

c. In addition to copies of applicable laws, the PI will provide documentation indicating:

(1) that cadavers will be properly and legally procured;

(2) that vendors will be informed of the intended use of the cadavers;

(3) that cadavers will be used in a manner consistent with the intent of the donor. Any restrictions on the use of cadavers by the donor must be honored in the protocol. The wishes of donor's next of kin will be considered if and as required by applicable laws; and

(4) that cadavers were tested for at least the following communicable diseases: hepatitis B and HIV. The documentation must indicate whether tests were positive for any cadaver, and if so, for what diseases. Research staff and any personnel who may come in contact with a cadaver that tested positive for a communicable disease must be made aware that the cadaver tested positive for the disease. Cadavers that test positive for given diseases may or may not be appropriate for the research protocol in question; it is not expressly prohibited to use in research cadavers that have tested positive. If the PI believes that testing is impossible or unnecessary for a given protocol, the PI must provide an explanation that satisfies the HURC/IRB and HSRRB.

d. Protocols involving the use of human cadavers will include specific procedures for the treatment, storage, and disposal of human cadavers by the research staff and other institution personnel. The HURC and HSRRB must be satisfied that these procedures are appropriate and ethical. For example, the HURC and HSRRB should consider whether the protocol provides for proper transportation and refrigeration of cadavers; whether the protocol limits access to cadavers to those with a need for access and provides for security of the cadavers; whether the protocol provides for disposal of the cadavers in accordance with stated wishes of the donor or next of kin; and whether the protocol provides for maintaining confidentiality of identity of cadavers. While compliance with state and local laws may often or sometimes be sufficient to satisfy the HURC or HSRRB as to the ethical treatment of the cadavers, there may be certain research protocols (or certain states) for which measures beyond mere compliance with

state and local laws are deemed necessary to ensure that cadavers are treated ethically.

e. The HURC and the HSRRB will only approve research using human cadavers if:

(1) the research cannot be successfully conducted without using human cadavers; and

(2) benefits of the research are significant enough to justify the use of human cadavers; and

(3) the protocol considers whether there is a likelihood of psychological harm to research staff and other personnel due to the nature of the work with human cadavers in the protocol, and, if so, whether the protocol has procedures in place to minimize such harm. The HURC/IRB and HSRRB will determine if the protocol should include a consent document that informs research staff and other personnel of the nature of the experiment, the use of human cadavers, and the possible risk of mental or emotional distress due to involvement in the experiment. Such a consent form may not be necessary in all protocols involving human cadavers.

f. The HURC or the HSRRB may require researchers to undergo training on ethical issues in human cadaver research. If it requires such training, the HURC or the HSRRB must specify what training it feels is necessary. The PI must then provide evidence that this training has been completed.

7. Implementation. Laboratory/Institute commanders will ensure that research involving human cadavers does not commence prior to notification of final approval of the HSRRB. DOD-sponsored extramural research involving human cadavers cannot commence until final approval of HSRRB is received by the institution through the Contract Officer/Specialist, USAMRAA.

Julie K. Zadinsky

Encl

JULIE K. ZADINSKY
COL, AN
Acting Chair, Human Subjects
Research Review Board

MCMR-RCQ
SUBJECT: HSRRB Policy Memorandum 2002-05, Ethical Use of Human Cadavers in Research

RECOMMEND APPROVAL/~~DISAPPROVAL~~

DATE: 27 AUG 02
LESTER MARTINEZ-LOPEZ
Major General, MC
Chair, Human Subjects
Research Review Board

APPROVED/~~DISAPPROVED~~

FOR THE SURGEON GENERAL:

DATE: 28 Aug 02
KENNETH L. FARMER, JR.
Major General
Deputy Surgeon General

APPENDIX A
HSRRB Policy Memorandum History

Version Number: 01

Version Date:

Effective Date:

Reason for Revisions: This is the initial policy.

Detailed List of Changes: N/A

APPENDIX B

HSRRB HUMAN CADAVER PROTOCOL CHECKLIST

HSRRB Human Cadaver Protocol Checklist

HSRRB Log No. _____

Date Checklist Completed: _____ PI: _____

Date Checklist Updated: _____ Reviewer's Signature: _____

Elements	Is Element Addressed?			Comments
	Yes	No	N/A	
A. Intramural research protocols are reviewed & approved by:				
1. Scientific Review Committee or equivalent.				
2. HURC and Commander.				
B. Extramural research protocols are reviewed & approved by:				
1. Scientific Review Committee.				
2. Local IRB if it is the policy of that IRB to review human cadaver research or institutional official if the institution does not require IRB approval.				
C. The PI has provided copies of state and local laws (or, for research in a foreign country or U.S. territory, that country's or territory's laws) regarding procurement, treatment, and disposition of cadavers, and the research protocol is in compliance with these laws.				
D. The PI has provided documentation that indicates:				
1. Cadavers will be properly and legally procured.				
2. Vendors will be informed of the intended use of cadavers.				
3. Cadavers will be used in a manner consistent with the donor's intent.				
4. Cadavers will be tested for Hepatitis B and HIV.				
E. The PI has provided a description of procedures for informing research staff of positive communicable disease test results.				
F. There will be appropriate and ethical treatment of cadavers as evidenced by:				
1. Appropriate procedures for proper transportation and refrigeration of cadavers are in place.				
2. Access to cadavers is limited to those who need it.				

HSRRB Human Cadaver Protocol Checklist

HSRRB Log No. _____

Elements	Is Element Addressed?			Comments
	Yes	No	N/A	
3. Appropriate procedures for cadaver security are in place.				
4. Appropriate procedures for disposal of cadavers in accordance with wishes of donor or next of kin are in place.				
5. Appropriate procedures for maintaining confidentiality of cadavers are in place.				
G. Sample size justification demonstrates that the proposed number of cadaver specimens is the minimum needed to achieve the research objectives.				
H. Research meets the following criteria:				
1. The research cannot be successfully conducted without the use of human cadavers.				
2. Benefits of research are significant enough to justify the use of human cadavers.				
3. The likelihood of psychological harm to research staff and other personnel due to work with cadavers has been considered and appropriate procedures are in place to minimize psychological harm.				
I. Additional requirements as deemed necessary by the HSRRB/IRB:				
1. An appropriate informed consent document for research staff and other personnel. The consent document should describe the nature of the experiment, the use of human cadavers, and the possible risk of mental or emotional distress due to involvement in the experiment.				
2. Training for researchers on ethical issues in human cadaver research as specified by the HURC or HSRRB.				

Additional Comments